Claims

1. Pharmaceutical composition, characterised in that it contains an anticholinergic of the formula **1**

wherein

X - represents chlorine, bromine, iodine, methanesulphonate or trifluoromethanesulphonate;

R¹ represents hydroxy or methyl;

Ar represents phenyl or thienyl;

in combination with the compound of the formula 2

optionally in the form of a pharmacologically acceptable acid addition salt thereof, optionally in the form of a solvate or hydrate and optionally together with a pharmaceutically acceptable excipient.

2. Pharmaceutical composition according to claim 1, characterised in that the anticholinergic of the formula 1 is a compound of the formula 1a

wherein

X - represents chlorine, bromine, iodine, methanesulphonate or trifluoromethanesulphonate,

optionally in the form of a pharmacologically acceptable acid addition salt thereof, optionally in the form of a solvate or hydrate and optionally together with a pharmaceutically acceptable excipient.

- 3. Pharmaceutical composition according to claim 2, characterised in that X represents bromine.
- 4. Pharmaceutical composition according to claim 1, characterised in that the anticholinergic of the formula 1 is a compound of the formula 1b

wherein

X - represents chlorine, bromine, iodine, methanesulphonate or trifluoromethanesulphonate,

optionally in the form of a pharmacologically acceptable acid addition salt thereof, optionally in the form of a solvate or hydrate and optionally together with a pharmaceutically acceptable excipient.

- 5. Pharmaceutical composition according to claim 4, characterised in that X represents bromine.
- 6. Pharmaceutical composition according to one of claims 1 to 5, characterised in that the anticholinergic of the formula 1 and the compound of the formula 2 are present either together in a single formulation or in two separate formulations.
- 7. Pharmaceutical composition according to one of claims 1 to 6, characterised in that the weight ratios of the anticholinergic of the formula <u>1</u> to the compound of the formula <u>2</u> are in the range from 1:4000 to 8:1, preferably from 1:1000 to 1:1.2.
- 8. Pharmaceutical composition according to one of claims 2 to 6, characterised in that the weight ratios of the compound of the formula <u>1a</u> to the compound of the formula <u>2</u> are in the range from 1:4000 to 1:2.5, preferably from 1:1000 to 1:12.5.
- 9. Pharmaceutical composition according to one of claims 4 to 6, characterised in that the weight ratios of the compound of the formula **1b** to the compound of the formula **2** are in the range from 1:4000 to 8:1, preferably from 1:1000 to 1:1.2.
- 10. Pharmaceutical composition according to one of claims 1 to 9, characterised in that the total dosage per single dose of the combination of the anticholinergic of the formula $\underline{1}$ and the compound of the formula $\underline{2}$ is in the range of 25 to $10000 \mu g$, preferably from 100 to $5800 \mu g$.
- 11. Pharmaceutical composition according to one of claims 1 to 10, characterised in that it is in the form of a formulation suitable for inhalation.
- 12. Pharmaceutical composition according to claim 11, characterised in that it is a formulation selected from among inhalable powders, propellant-

containing metering aerosols and propellant-free inhalable solutions or suspensions.

- 13. Pharmaceutical composition according to claim 12, characterised in that it is an inhalable powder which contains the anticholinergic of the formula 1 and the compound of the formula 2 in admixture with suitable physiologically acceptable excipients selected from among the monosaccharides, disaccharides, oligo- and polysaccharides, cyclodextrines, polyalcohols, salts, or mixtures of these excipients with one another.
- 14. Inhalable powder according to claim 13, characterised in that the excipient has a maximum average particle size of up to 250μ m, preferably between 10 and 150μ m.
- 15. Pharmaceutical composition according to claim 12, characterised in that it is an inhalable powder which contains only the anticholinergic of the formula **1** and the compound of the formula **2** as its ingredients.
- 16. Pharmaceutical composition according to claim 12, characterised in that it is a propellant-containing inhalable aerosol which contains the anticholinergic of the formula <u>1</u> and the compound of the formula <u>2</u> in dissolved or dispersed form.
- 17. Pharmaceutical composition in the form of a propellant-containing inhalable aerosol according to claim 16, characterised in that it contains, as propellant gas, hydrocarbons such as n-propane, n-butane or isobutane or halohydrocarbons such as chlorinated and/or fluorinated derivatives of methane, ethane, propane, butane, cyclopropane or cyclobutane.
- 18. Pharmaceutical composition in the form of a propellant-containing inhalable aerosol according to claim 17, characterised in that the propellant gas is TG11, TG12, TG134a (1,1,1,2-tetrafluoroethane), TG227 (1,1,1,2,3,3,3-heptafluoropropane) or a mixture thereof.
- 19. Pharmaceutical composition according to claim 12, characterised in that it is a propellant-free inhalable solution or suspension which contains water, ethanol or a mixture of water and ethanol as solvent.

- 20. Pharmaceutical composition in the form of an inhalable solution or suspension according to claim 19, characterised in that the pH is 2 to 7, preferably 2 to 5.
- 21. Capsules, characterised in that they contain an inhalable powder according to claim 13 or 14.
- 22. Use of a capsule according to claim 15 in an inhaler, preferably in a Handyhaler.
- 23. Use of an inhalable solution according to one of claims 19 or 20 for nebulising in an inhaler, preferably according to WO 91/14468 or an inhaler as described according to the Figures 6a and 6b of WO 97/12687.
- 24. Use of a composition according to one of claims 1 to 20 for preparing a medicament for treating pulmonary diseases, in particular inflammatory or obstructive diseases of the respiratory tract.
- 25. A method of prophylaxis of, treating of, or reducing the exacerbations associated with pulmonary diseases by administering to a patient in need thereof an effective amount of a pharmaceutical composition according to one or more of the claims 1 to 20 either in a single combined form, separately, or separately and sequentially where the sequential administration is close in time, or remote in time.
- 26. The method according to claim 25 wherein the pulmonary disease is asthma, COPD, or another obstructive airways disease exacerbated by bronchial hyperreactivity and bronchospasm.
- 27. The method according to claim 25 or 26 wherein said administration by inhalation comprises simultaneous or sequential delivery of said combination of therapeutic agents, comprising the anticholinergic of the formula **1** and the compound of the formula **2**, in the form of an aerosol or dry powder dispersion.
- 28. The method according to one or more of the claims 25 to 27, wherein the anticholinergic of the formula $\underline{1}$ is the compound of the formula $\underline{1a}$.

- 29. The method according to one or more of the claims 25 to 27, wherein the anticholinergic of the formula **1** is the compound of the formula **1b**.
- 30. A package comprising a pharmaceutical composition according to one or more of the claims 1 to 22 for insertion into a device of simultaneous or sequential delivery of said pharmaceutical composition in the form of an aerosol or dry powder dispersion, to a mammal in need of treatment.
- 31. Inhaler comprising a pharmaceutical composition according to one or more of the claims 1 to 22 for simultaneous or sequential delivery of said pharmaceutical composition in the form of an aerosol or dry powder dispersion, to a mammal in need of treatment.
- 32. Pharmaceutical composition, characterised in that it contains an anticholinergic in combination with the compound of the formula **2** optionally in the form of a pharmacologically acceptable acid soldition salt thereof, optionally in the form of a solvate or hydrate and optionally together with a pharmaceutically acceptable excipient.
- 33. An agent for prophylactic and/or therapeutic treatment of pulmonary diseases, in particular inflammatory or obstructive diseases of the respiratory tract, which comprises the pharmaceutical composition according to one of claims 1 to 20.
- 34. An agent for prophylactic and/or therapeutic treatment of pulmonary diseases, in particular inflammatory or obstructive diseases of the respiratory tract, which comprises the pharmaceutical composition according to one of claims 1 to 20 for administering either in a single combined form, separately, or separately and sequentially where the sequential administration is close in time, or remote in time.
- 35. The agent according to claim 34 wherein the pulmonary disease is asthma, COPD, or another obstructive airways disease exacerbated by bronchial hyperreactivity and bronchospasm.
- 36. The agent according to claims 33 to 35, wherein the anticholinergic of the formula $\underline{\mathbf{1}}$ is the compound of the formula $\underline{\mathbf{1a}}$.

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37. The agent according to claims 33 to 35, wherein the anticholinergic of the formula $\underline{\mathbf{1}}$ is the compound of the formula $\underline{\mathbf{1}}$.